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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/623,480	07/18/2003	Cory M. Panattoni	002558-068710US	4555		
20350	7590 01/10/2005		EXAMINER			
	TOWNSEND AND TOWNSEND AND CREW, LLP TWO EMBARCADERO CENTER EIGHTH FLOOR			OLSEN, KAJ K		
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DATE MAILED: 01/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	10
Office Astina Occurs		10/623,480	PANATTONI, CORY M.	
	Office Action Summary	Examiner	Art Unit	
		Kaj K Olsen	1753	
Period f	The MAILING DATE of this communication app for Reply	ears on the cover sheet wit	h the correspondence address	
THE - Extended - If th - If No - Fail Any	MAILING DATE OF THIS COMMUNICATION. ensions of time may be available under the provisions of 37 CFR 1.13 or SIX (6) MONTHS from the mailing date of this communication. he period for reply specified above is less than thirty (30) days, a reply o period for reply is specified above, the maximum statutory period value to reply within the set or extended period for reply will, by statute, or reply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	36(a). In no event, however, may a re y within the statutory minimum of thirty vill apply and will expire SIX (6) MONT , cause the application to become ABA	ply be timely filed (30) days will be considered timely. FHS from the mailing date of this communic ANDONED (35 U.S.C. § 133).	cation.
Status				
1)⊠	Responsive to communication(s) filed on 01 N	ovember 2004.		
·	<u> </u>	action is non-final.		
3)□	ers, prosecution as to the merit	ts is		
	closed in accordance with the practice under E	x parte Quayle, 1935 C.D.	11, 453 O.G. 213.	
Disposit	tion of Claims			
4)⊠	Claim(s) 1-33 is/are pending in the application.			
	4a) Of the above claim(s) is/are withdraw	wn from consideration.		
5)□	Claim(s) is/are allowed.			
6)⊠	Claim(s) <u>1-33</u> is/are rejected.			
7)	Claim(s) is/are objected to.			
8)[Claim(s) are subject to restriction and/or	r election requirement.		
Applicat	tion Papers			
9)[The specification is objected to by the Examine	r.		
10)	The drawing(s) filed on is/are: a)☐ acce	epted or b) objected to b	y the Examiner.	
	Applicant may not request that any objection to the	drawing(s) be held in abeyand	e. See 37 CFR 1.85(a).	
	Replacement drawing sheet(s) including the correct	ion is required if the drawing(s	s) is objected to. See 37 CFR 1.12	21(d).
11)[The oath or declaration is objected to by the Ex	aminer. Note the attached	Office Action or form PTO-152	2.
Priority	under 35 U.S.C. § 119			
a)	Acknowledgment is made of a claim for foreign All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priority documents application from the International Bureau	s have been received. s have been received in Aprity documents have been rule (PCT Rule 17.2(a)).	oplication No received in this National Stage	ı
* (See the attached detailed Office action for a list	of the certified copies not r	eceived.	
Attachmer	nt(s)			
	ce of References Cited (PTO-892)		immary (PTO-413)	
3) 🔲 Infor	ce of Draftsperson's Patent Drawing Review (PTO-948) rmation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) er No(s)/Mail Date		/Mail Date formal Patent Application (PTO-152) -	

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4, 7, 8, 11-21, 23-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 7-14, 16, 17 and 19-26 of copending Application No. 10/346,681 in view of any of Sylvester et al (USP 5,837,288), Alpenfels et al (USP 5,753,095), Bluestein et al (USP 4,209,373), Monte et al (USP 4,314,897) or Takeda et al (USP 5,464,516). Although the conflicting claims are not identical, they are not patentably distinct from each other. With respect to these various claims, the examiner addressed in the previous office action how these claims were not patentably distinct from those of 10/346,681. Upon amendment, applicant has now inserted the language that the slab gel be stored for at least 5 days. However, it is well known that being able to store a gel for a long period of time is useful because it would require the gels to be prepared just prior to the electrophoresis. Sylvester demonstrates this by specifying that their particular storage method allows a gel to be stored for six months or more. See col. 2, lines 26-38. Alpenfels teaches the use of a container that allows gels to be stored for at least five days with no

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significant deterioration is gel quality. See col. 7, lines 58-67. Bluestein teaches that if gels are kept cold and sealed, they can be stored for at least six months. See col. 4, lines 9-16. Monte teaches that moisture proof sealing would allow for storage of two years. See col. 3, lines 50-54. Takeda teaches that storage of a gel at 5 °C for 120 days did not change the properties of the gel. Compare tables 2 and 3 in col. 8. These references all individually demonstrate that keeping gels in storage for extending periods of time (including over 5 days) was both desired and required only routine skill in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize any of the teachings of Sylvester, Alpenfels, Bluestein, Monte or Takeda for the methods or slab gel of 10/346,681 so that gels need not be prepared just prior to electrophoretic analysis.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- Claims 18-30 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, 4. under 35 U.S.C. 103(a) as obvious over Ogawa (USP 4,657,656).
- 5. Ogawa '656 discloses a pre-cast polyacrylamide slab gel that comprises placing a gelforming liquid mixture in a gel enclosure defined by a pair of chemically inert (i.e. glass) plates,

where the gel-forming mixture comprises acrylamide monomer, cross-linking agent, buffer, and a water soluble polymer such as polyethylene glycol and polyvinyl alcohol, and polymerizing the gel mixture. See abstract; col. 3, lines 16-32; col. 4, lines 60-68 and table I in col. 5. The present invention evidences that these polymers utilized by Ogawa '656 are inherently nonionic amphiphilic polymers (claims 8 and 11). Although Ogawa '656 does not explicitly set forth that the glass plates utilized are transparent, it presumably is because glass is conventional transparent and dye patterns can be observed through the glass (col. 5, lines 33-35). Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize a transparent form of glass so that the gelation can be visually observed.

6. With respect the to new limitation about the gels being formed at least 5 days prior to the electrophoresis, the storage of the gel prior to electrophoresis constitutes either the process of using the gel or the process for preparing the gel itself. If the storage is interpreted as a process of using, that is only the intended use of the apparatus and the intended use need not be given further due consideration in determining patentability. If the storage is interpreted as a process of preparing the gel, the determination of patentability for the claim is based on the product itself. Because the product of the claim is identical to the invention of Ogawa '656 the process from which it was made is the same as or obvious over the process utilized by Ogawa '656 (see *In re Thorpe*, 777 F.2d 695, 698). This is especially evident from the fact that the slab gel of Ogawa '656 read on the slab gel of instant invention. If the instant inventors determined that the gels of instant invention can withstand over 5 days of storage prior to use, then the gels of

Ogawa '656 would presumably also be able to withstand over 5 days of storage prior to use regardless of whether Ogawa '656 recognized this.

- With respect to the claimed molecular weight, see table I and col. 3, lines 25-27. With respect to the claims molecular weights of claims 19-22, 25 and 28, it appears that col. 3, lines 25-27 teaches those ranges with sufficient specificity to meet the claimed invention. In particular, Ogawa teaches the use of 800,000 (table I), which falls in the range of 100,000 to any of 8,000,000; 5,000,000; or 1,000,000. Alternatively, if the specified range of col. 3, lines 25-27 were interpreted as not meeting these limitations of "200 to about 20,000" with sufficient specificity, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize 200 to 20,000 molecular weight provided one desired a gel having viscosity on the lower end of the range (see col. 3, lines 38-41).
- 8. With respect to the claimed amount of nonionic amphiphilic polymer, see Ogawa '656, col. 3, lines 29-31. With respect to the particular claimed range of claim 22, although Ogawa '656 lower range point is 1%, Ogawa '656 is an improvement over a prior art that added no amphiphilic polymer to the gel. Hence, if one only wanted to add a small amount of elasticity to the gel and is willing to tolerate a degree of brittleness, one would have been motivated to utilized an even smaller amount of amphiphilic polymer in order to arrive at a gel having properties that lie between the properties of the gels of Ogawa '656 and the prior art that preceded it.

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Claim Rejections - 35 USC § 103

- 9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 10. Claims 1-14 and (18-30 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa '656 in view of Sylvester, Alpenfels, Bluestein, Monte or Takeda.
- 11. Ogawa '656 discloses a method of manufacturing a pre-cast polyacrylamide slab gel that comprises placing a gel-forming liquid mixture in a gel enclosure defined by a pair of chemically inert (i.e. glass) plates, where the gel-forming mixture comprises acrylamide monomer, crosslinking agent, buffer, and a water soluble polymer such as polyethylene glycol and polyvinyl alcohol, and polymerizing the gel mixture. See abstract; col. 3, lines 16-32; col. 4, lines 60-68 and table I in col. 5. The present invention evidences that these polymers utilized by Ogawa '656 are inherently nonionic amphiphilic polymers (claims 8 and 11). Although Ogawa '656 does not explicitly set forth that the glass plates utilized are transparent, it presumably is because glass is conventional transparent and dye patterns can be observed through the glass (col. 5, lines 33-35). Alternatively, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize a transparent form of glass so that the gelation can be visually observed.
- 12. The amended claims differ from the previous claims in setting forth storing the gels for at least 5 days. However, it is well known that being able to store a gel for a long period of time is useful because it wouldn't require the gels to be prepared just prior to the electrophoresis.

 Sylvester demonstrates this by specifying that their particular storage method allows a gel to be stored for six months or more. See col. 2, lines 26-38. Alpenfels teaches the use of a container

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that allows gels to be stored for at least five days with no significant deterioration is gel quality. See col. 7, lines 58-67. Bluestein teaches that if gels are kept cold and sealed, they can be stored for at least six months. See col. 4, lines 9-16. Monte teaches that moisture proof sealing would allow for storage of two years. See col. 3, lines 50-54. Takeda teaches that storage of a gel at 5 °C for 120 days did not change the properties of the gel. Compare tables 2 and 3 in col. 8. These references all individually demonstrate that keeping gels in storage for extending periods of time (including over 5 days) was desired and required only routine skill in the art. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize any of the teachings of Sylvester, Alpenfels, Bluestein, Monte or Takeda for the method or slab gel of Ogawa '656 so that gels need not be prepared just prior to electrophoretic analysis.

- 13. With respect to claims slab gel claims in the alternative, even if the gels of Ogawa '656 are deemed to not read on the claimed gel after 5 days of storage, Sylvester, Alpenfels, Bluestein, Monte or Takeda all teach means for preserving gels for long periods of time with little or any ill effect (see above) and it would have been obvious to one of ordinary skill in the art at the time the invention was being made to store the gel of Ogawa '656 by any of these means for at least 5 days so that gels need not be prepared just prior to electrophoretic analysis.
- 14. With respect to the claimed molecular weight, see table I and col. 3, lines 25-27. With respect to the claims molecular weights of claims 2-6, 9 and 12 (and 19-22, 25 and 28 in the alternative), it appears that col. 3, lines 25-27 teaches those ranges with sufficient specificity to meet the claimed invention. In particular, Ogawa teaches the use of 800,000 (table I), which falls in the range of 100,000 to any of 8,000,000; 5,000,000; or 1,000,000. Alternatively, if the specified range of col. 3, lines 25-27 were interpreted as not meeting these limitations of "200 to

about 20,000" with sufficient specificity, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize 200 to 20,000 molecular weight provided one desired a gel having viscosity on the lower end of the range (see col. 3, lines 38-41).

- 15. With respect to the claimed amount of nonionic amphiphilic polymer, see Ogawa '656, col. 3, lines 29-31. With respect to the particular claimed range of claim 9 (and claim 22 in the alternative), although Ogawa '656 lower range point is 1%, Ogawa '656 is an improvement over a prior art that added no amphiphilic polymer to the gel. Hence, if one only wanted to add a small amount of elasticity to the gel and is willing to tolerate a degree of brittleness, one would have been motivated to utilized an even smaller amount of amphiphilic polymer in order to arrive at a gel having properties that lie between the properties of the gels of Ogawa '656 and the prior art that preceded it.
- 16. Claims 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa '656 in view of Moi et al (USP 5,938,906).
- 17. Claims 15-17 (and 31-33 in the alternative) are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogawa '656 and any one of Sylvester, Alpenfels, Bluestein, Monte or Takeda in further view of Moi et al (USP 5,938,906).
- 18. Ogawa '656 (with or without Sylvester, Alpenfels, Bluestein, Monte or Takeda) set forth all the limitations of the claims, but did not explicitly recite the use of plastic. Moi teaches in an alternate gel cast that plastics, including styrene-acrylonitrile copolymers, can be utilized instead of glass for the gel casts. See col. 5, lines 8-30. Plastics have an advantage over glass in that they allow the cassette to be locked together (col. 5, lines 28-30). In addition, plastics are lighter,

easier to manufacture, and more resistant to shattering. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Moi for the method of gel of Ogawa '656 (with or without Sylvester, Alpenfels, Bluestein, Monte or Takeda) because plastics allow the cassette to be locked together, are lighter, easier to manufacture, and more resistant to shattering that glass cassette plates.

Response to Arguments

19. Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Thursday from 5:30 A.M. to 3:00 P.M. and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753 January 6, 2005

> KAJ K. OLBEN PRIMARY EXAMINER